

MAY 23 2001

11. Clinical Technology CT Spacer 510(k) Summary:

In accordance with 21 CFR section 807.92 Johnson is submitting the following safety and effectiveness summary.

1) Submitter Information

Robert Johnson, MD
705 E. Virginia Way, Suite I
Barstow, CA 92311
Telephone: (760) 256-2569

2) Name of Device

Proprietary Name: CT Spacer
Common Name is Handheld Spacer
Classification Name: Nebulizer Accessory

3) Substantially equivalent to: OptiHaler (Healthscan Products, Inc.), K911807.**4) Device Description and System Overview:**

The CT Spacer (Spacer) is an injection molded polycarbonate spacer device intended for use with FDA approved metered dose inhalers (MDI's) and FDA cleared nebulizers for the purpose of asthma treatment. One end of the CT Spacer serves as a mouthpiece, through which the patient will inhale aerosols generated either by a MDI or nebulizer product attached to the spacer. When a MDI is used it connects to other end of the hand-held spacer with a MDI boot and the third midline port allows for unobstructed airflow during inhalation. The boot is tapered in such a way that when the MDI canister is depressed, the MDI valve contacts the tapered portion of the boot, thereby activating a single dose of aerosol from the MDI. This is the same method of activation of the MDI and standard MDI boot provided with most MDI's.

When a nebulizer is used it connects to the smaller 18mm conical fitting midline port. A Valve Adapter may be used for nebulizers having exhaust ports ranging in size from 15mm to 22mm. When a nebulizer is used, the 22mm port opposite the mouthpiece vents to atmosphere.

The device is circular, light weight and can be easily held in one hand during use. The diameter of the Spacer increases from the ends to the middle of the device, so that the maximum diameter (device volume) is at the central part of the device. The additional internal volume of this design provides for an aerosol mixing chamber without adding unnecessarily to the bulk and weight of the device. The device is designed for use by all patients who have been prescribed nebulizer or MDI treatment. Use of the device is obvious and clearly described in product labeling.

A metered dose inhaler or a nebulizer can be introduced into the Spacer utilizing a single injection port (as noted) so that medicinal aerosols generated by those devices can be introduced into the spacer for subsequent inhalation by the patient. A

patented Valve Adapter is used to accommodate nebulizer devices with 15 and 22mm exhaust ports. The Valve Adapter and all Spacer ports have been designed to meet the design requirements of ASTM Specification F 1054: "Specifications for Conical Fittings of 15mm and 22mm Sizes."

The product is sold non-sterile, and is a single-patient device intended to be used for up to 28 days. Labeling reflects sterility, cleaning and use of the device. All materials used in the manufacturing of this device are used in predicate devices, including the predicate Optihaler device used in comparative product testing of the CT Spacer.

This device does not generate aerosols. Its purpose is to provide an effective mixing chamber for the aerosols produced by either a nebulizer or a metered dose inhaler to assure better aerosol distribution and concentration prior to inhalation by the patient. This is a prescription device.

The device has no detection capabilities. It is mechanical and has no alarm functions or capabilities. There is no software integrated or used in conjunction with this device.

Product testing has been completed according to the "Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators (10-01-93)." Product testing performed by Dr. Johnson provides clear proof that the CT Spacer is superior to the MDI or nebulizer alone, and is comparable or superior to the predicate device tested. The premarket notification submitted to FDA contains a full discussion of product testing, which includes delivered aerosol potency, MMAD, GSD, particle distribution, retained aerosols (undelivered aerosols due to rain-out within the device during MDI activation or nebulizer use) and life testing. All tests included comparative testing of the MDI, the OptiHaler and the CT Spacer. Nebulizer aerosol tests were also performed and summarized.

Aerosol released by the activated MDI or nebulizer enters the larger circular cavity of the CT Spacer and mixes evenly within the spacer volume. Because of the circular shape and progressively smaller area within the conical ends of the CT Spacer, the aerosol tends to flow in a circular manner, filling the chamber from the central maximum diameter towards the smaller outer diameters of the spacer. Because of the enhanced mixing of released aerosol with ambient air within the spacer, there is no requirement for a baffle, deflector or secondary jet within the spacer to deflect the aerosols generated by MDI activation. This, in turn, reduces the amount of "rain-out" of medical aerosols and maximizes the amount of usable drug delivered through the CT Spacer mouthpiece.

Residual levels of all drugs tested in the CT Spacer devices were lower than the MDI, nebulizer or competitive predicate device tested.

The MDI/Nebulizer port can be sealed with plastic cap, which forms a primary seal for the device when a MDI or nebulizer is not being used.

The CT Spacer does not augment or affect nebulizer aerosol generation or performance. Aerosol size was equivalent in all devices tested.

Design Considerations and Operation of the Device:

The device is intended to be used with FDA approved MDI drugs and FDA cleared nebulizer products. The 22 mm mouthpiece and open air ends of the device meet ASTM Designation F 1054-87, "Standard Specifications for Conical Fittings of 15mm and 22mm Sizes," published 9-87. The Spacer is made from polycarbonate plastic, and is equivalent to the predicate OptiHaler device tested. This material is used routinely in devices such as nebulizers and other aerosol component devices, including spacers, mouthpieces and tubing connectors.

Testing:

All product and comparative in vitro testing performed was based upon the requirements of the "Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators: Reviewer Guidance 10-01-93." Testing was conducted by an independent medical device manufacturer and test laboratory contracted by Dr. Johnson. All tests were performed according documented test protocol.

The following tests were completed for the CT Spacer, the OptiHaler and stand-alone MDI assemblies and nebulizers specified in this premarket notification:

- Particle size distribution
- Dose output testing (drug quantity and total mass using 3 drugs)
- Mean median aerodynamic diameter (MMAD)
- Geometric standard deviation (GSD)
- Plume Testing
- Single patient use testing (life testing)
- In addition, nebulizer aerosol testing was also performed comparing the CT Spacer and nebulizer tested.

No clinical testing was performed on this product. Please refer to the attached table for a summary of comparative in vitro laboratory testing results.

Software Validation: Not applicable: there is no software in this product.

Sterilization Validation: Not applicable: this product is sold and used as a non-sterile product.

Biocompatibility: All materials used in this device are incorporated in other predicate devices, as well as nebulizers, connectors and mouthpieces currently sold in the marketplace, and are therefore appropriate for the intended use described herein.

Table 1 510(k) Summary Comparative Product Test Results:

	Clinical Technology	Healthscan Products, Inc.	MDI	Nebulizer
Test or Characteristic:	CT Spacer	OptiHaler	Various: noted in protocol	VixOne
Model #:	To be determined	765-10	various	VixOne
Meets ASTM Specification F 1054	Yes	Yes	NA	Yes
Normalized Respirable Dose: MDI with Aerobid	75-80%	76%	75%	NA
Normalized Respirable Dose: MDI with Proventil	87-89%	85%	77%	NA
Normalized Respirable Dose: MDI with Vanceril	55-65%	53%	60%	NA
Normalized Respirable Dose: VixOne Nebulizer with Proventil	62%	NA	NA	51%
Dose Output Data (μg flunisolide)	58 \pm 15	38 \pm 4	49 \pm 8	NA
Dose Output Data (μg flunisolide) Throat	6 \pm 2	4 \pm 1	88 \pm 17	NA
Dose Output Data (μg proventil)	51 \pm 15	15 \pm 3	27 \pm 3	NA
Dose Output Data (μg proventil) Throat	0.8 \pm 0.2	0.6 \pm 0.1	28 \pm 5	NA
Dose Output Data (μg vanceril)	19 \pm 3	15 \pm 3	14 \pm 1	NA
Dose Output Data (μg vanceril) Throat	6 \pm 1	8 \pm 6	31 \pm 2	NA
MMAD Aerobid (MDI)	1.72-1.90	1.81	1.96	NA
GSD Aerobid (MDI)	1.92-2.11	2.09	2.12	NA
MMAD Proventil (MDI)	1.18-1.23	1.07	1.07	NA
GSD Proventil(MDI)	1.65-1.71	1.93	1.69	NA
MMAD Vanceril (MDI)	1.58-1.73	1.75	2.02	NA
GSD Vanceril (MDI)	2.43-2.90	2.65	2.87	NA
MMAD Proventil (nebulizer)	1.14	NA	NA	0.81
GSD Proventil (nebulizer)	2.62	NA	NA	2.45
Use Testing Dose Output:				
Start	126	NA	NA	NA
Middle	114	NA	NA	NA
End	162	NA	NA	NA

Comparative Product Matrix

Table 2: 510(k) Summary - Substantial Equivalence to Predicate Devices

item:	Characteristic:	Clinical Technology	Healthscan Products, Inc.	Thayer Medical, Inc.
	Model:	CT Spacer	OptiHaler	Medi-Spacer
1.	Product meets ASTM F 1054 for 15 & 22 mm connector	Yes	Yes	Yes
2.	Nebulizer Port?	Yes	No	No
3.	MDI Port?	Yes	Yes	Yes
4.	Spacer Material	Clear Polycarbonate	Clear Polycarbonate	Clear Polycarbonate
5.	Single Patient Use?	Yes	Yes	Yes
6.	Sterility?	Non-Sterile	Non-Sterile	Non-Sterile
7.	Ventilator Use?	No	No	Yes
8.	Maximum Length of Use:	Single patient up to 28 days	<u>Single patient</u>	<u>Single patient</u>
8.	Effective Size of mixing area:	Approximately 120 ml	Approximately 90 ml	Approximately 130ml
9.	Method of Operation:	Mechanical	Mechanical	Mechanical
10.	Prescription Device?	Yes	Yes	Yes
11.	Provided as Kit?	No	No	No
12.	Protective caps on ports?	Yes	Yes	Yes
item:	Characteristic:	Johnson	Healthscan Products, Inc.	Thayer Medical, Inc.
	Model:	Spacer	OptiHaler	Medi-Spacer
	Premarket Submission:	Pending	(K911807)	(K955805).
1.	Product meets ASTM F 1054 for 15 & 22 mm connector	Yes	Yes	Yes
2.	Nebulizer Port?	Yes	No	No
3.	MDI Port?	Yes	Yes	Yes
4.	Spacer Material	Clear Polycarbonate	Clear Polycarbonate	Clear Polycarbonate
5.	Single Patient Use?	Yes	Yes	Yes
6.	Sterility?	Non-Sterile	Non-Sterile	Non-Sterile
7.	Ventilator Use?	No	No	Yes
8.	Maximum Length of Use:	Single patient up to 28 days	Single patient	Single patient
8.	Effective Size of mixing area:			
9.	Method of Operation:	Mechanical	Mechanical	Mechanical
10.	Prescription Device?	Yes	Yes	Yes
11.	Provided as Kit?	No	No	No
12.	Protective caps on ports?	Yes	Yes	Yes

Conclusions of all Testing: The Clinical Technology Spacer met all design requirements and passed all validation and comparative product testing. The device is manufactured from the same materials used in the predicate device tested and performance in all in vitro tests was equivalent or superior to the comparative predicate device tested.

Based upon these results, it is our conclusion that the CT Spacer is as safe, as effective and performs as well as or better than the legally marketed predicate OptiHaler Spacer device used in comparative product testing.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2001

Robert Johnson, M.D.
Clinical Technology, Inc.
705 E. Virginia Way, Suite 1
Barstow, CA 92311

Re: K010680
CT Spacer
Regulation Number: 868.5630
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: February 19, 2001
Received: March 7, 2001

Dear Dr. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

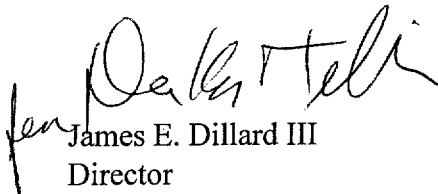
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III", is written over the typed name.

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K010680

Device Name: CT Spacer

Indications For Use: The CT Spacer is a spacer used with an MDI or a nebulizer to deliver inhalable drug aerosols to a patient. The spacer is to be used by a single patient, for a maximum of 28 days.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K010680

(Optional Format 3-10-98)

☒ PRESCRIPTION
USE

or

☐ OVER-THE-
COUNTER